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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/511,987 | 10/21/2004 | Judith Aronhime | 1662/58602 | 8819 |

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| EXAMINER | |
|---|---|
| LAO, MARIALOUISA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1621 | |

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/511,987 | ARONHIME ET AL. | |
| | Examiner | Art Unit | |
| | MLouisa Lao | 1621 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102/103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiskett et al. (USPat 5,861,179). In col1 lines 13-67, col2 lines 1-67, col3 lines 22-29 and col3 lines 58-60, Hisket et al. disclose the powder formulations of lamotrigene...with average particle sizes... below 125μm. In col1 lines 5-10, Hisket et al. teach the pharmaceutical compound

lamotrigene, the pharmaceutical formulation of lamotrigene and pharmaceutically acceptable acid addition salts thereof.

The '179 patent reads on the instant application's claims 3-5 and 8-15, which recite the pharmaceutical composition of lamotrigene spanning particle sizes of 100μm, 50μm and 10μm as well as solid oral dosage form. See Examples.

The '179 patent also reads on the use of the lamotrigene as recited in the instant claims 25 and 26. See column 1, lines 9-13.

Hisket et al. is silent on a plurality of lamotrigene particles having a specific surface area as recited on the instant claims 1, 2, 6 and 7. However, a compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Since there is a relationship between particle diameter and specific surface area, reduced particle size inherently leads to increased surface area, an artisan with ordinary skill in the art at the time of the invention would know and is logically motivated to apply known particle size reduction techniques as these are well known optimization steps both in the art and as taught by the prior art with a reasonable expectation that these efforts will attain the desired particle and/or granular size as in the instant claimed application. And the artisan of ordinary skill in the art would know that the reduced size would logically parlay to an increased specific surface area.

It is *prima facie* case obvious to combine the teachings of the '179 patent with the well established relationship between specific surface area and average particle diameter in order to achieve the characteristics of the plurality of lamotrigene particles. Further, one of ordinary skill in the art would have been motivated to optimize the

particle size of the lamotrigene particles because the optimization step is considered well in the competence level of an ordinary skilled artisan in the pharmaceutical science, involving merely routine skill in the art. Furthermore, it is within the skill in the art to select optimal parameters, such as amount of ingredients, granular size and specific surface area, in a composition in order to achieve a beneficial effect of increased dissolution.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the '179 patent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiskett et al. (US Pat 5,861,179) in view of Sawyer et al. (US Pat. 4,602,017). In col1 lines 13-67, col2 lines 1-67, col3 lines 22-29 and col3 lines 58-60, Hisket et al. disclose the powder formulations of lamotrigene...with average particle sizes... below 125μm. In col1 lines 5-10, Hisket et al. teach the pharmaceutical compound lamotrigene, the pharmaceutical formulation of lamotrigene and pharmaceutically acceptable acid addition salts thereof in solid form. Sawyer et al. teaches the use of compounds of the general formula (III), which embraces lamotrigene, for the treatment of CNS disorders.

Further, the '017 patent teaches the use of said compounds in pharmauceutical formulations which can be administered in liquid or solid form. See column 3, lines 18-68 through column 4, lines 1-31. It would have been obvious for one skilled in the art to apply the teachings of Sawyer et al. for liquid formulations to the Hisket et al. solid pharmaceutical formulation of lamotrigene in order to arrive to the claimed liquid oral dosages of claims 16-24.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art is indicative of the level of the art, which show that optimization techniques to achieve desired particle sizes and the pharmaceutical compound - lamotrigene, its pharmaceutical compositions and its use are well known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao, whose telephone number is 571-272-9930. The examiner can normally be reached on Monday to Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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